

**IN THE UNITED STATES DISTRICT
COURT DISTRICT OF MINNESOTA**

<i>IN RE BAYCOL PRODS. LITIG.</i>)	<u>ANSWER AND</u>
)	<u>AFFIRMATIVE DEFENSES</u>
This Document Relates to:)	
)	
<i>United States ex rel. Simpson v.</i>)	JURY TRIAL DEMANDED
<i>Bayer Healthcare, et al.,</i>)	
MDL Case No. 0:08-cv-5758)	MDL No. 1431 (MJD/SRN)
)	

Defendants Bayer Corporation, Bayer AG, and Bayer Healthcare Pharmaceuticals, Inc., hereinafter collectively “Bayer” (except as otherwise noted), by and through its counsel of record, respectfully submits this Answer and Affirmative Defenses to Relator Laurie Simpson’s Second Amended Complaint (“SAC”).

ANSWER TO ALLEGATIONS

1. Bayer admits that the Complaint alleges violations of the False Claims Act (“FCA”), but denies that any such conduct occurred, and otherwise denies the allegations in Paragraph 1 of the SAC.
2. Bayer admits that Relator seeks to recover damages arising from alleged violations of the FCA, but denies that any violations entitling the Realtor to damages arising under the FCA occurred, and otherwise denies the allegations in Paragraph 2 of the SAC.
3. Bayer admits that Baycol was Bayer’s U.S. trade name for cerivastatin, and admits that Bayer was approved to treat and lower cholesterol. Bayer admits that Baycol was the sixth statin approved for medical use, and that it launched in January 1998. Bayer

admits that it voluntarily withdrew Baycol from the U.S. Market in 2001. Bayer otherwise denies the allegations in Paragraph 3 of the SAC.

4. Bayer admits that Bayer voluntarily removed Baycol from the market, but otherwise denies the allegations in Paragraph 4 of the SAC.

5. Bayer admits that it contracted with the Department of Defense for the purchase Baycol, but otherwise denies the allegations in Paragraph 5 of the SAC.

6. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no answer to Paragraph 6 is required. To the extent an answer is required, Bayer denies the allegations contained in Paragraph 6 of the SAC.

7. Bayer admits that the Relator was employed by Bayer as a Senior Market Research Analyst, but otherwise denies the allegations contained in Paragraph 7 of the SAC

8. Bayer denies the allegations contained in Paragraph 8 of the SAC.

9. Bayer denies the allegations contained in Paragraph 9 of the SAC.

10. Bayer admits that the Relator participated in some Baycol Project Team meetings associated with marketing the product Baycol, but otherwise denies the allegations contained in the SAC. Bayer further states that to the extent that Paragraph 10 summarizes the content of a document, that document speaks for itself and no response is required.

11. Bayer denies the allegations contained in Paragraph 11 of the SAC.

12. Bayer denies the allegations contained in Paragraph 12 of the SAC.

13. Bayer denies the allegations contained in Paragraph 13 of the SAC. Bayer further states that to the extent that Paragraph 13 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

14. Bayer denies the allegations contained in Paragraph 14 of the SAC.

15. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no answer to Paragraph 15 is required. To the extent that a response is deemed necessary, Bayer denies the allegations contained in Paragraph 15 of the SAC.

16. Paragraph 16 states legal conclusions to which no answer is required. To the extent that an answer to the allegations contained in Paragraph 16 of the SAC is required, Bayer denies the allegations.

17. Bayer denies the allegations contained in Paragraph 17 of the SAC.

18. Paragraph 18 of the SAC states legal conclusions to which no response is required. To the extent that a response is deemed necessary, Bayer states that the statutes referred to in Paragraph 18 of the SAC speak for themselves, and no response is required.

19. Paragraph 19 of the SAC recites legal conclusions to which no response is required. To the extent that a response is deemed necessary, Bayer states that the statute referred to in Paragraph 19 of the SAC speaks for itself, and that Bayer does not dispute that this Court has personal jurisdiction.

20. Paragraph 20 of the SAC recites legal conclusions to which no response is required. To the extent that a response is deemed necessary, Bayer states that the statute

referred to in Paragraph 20 of the SAC speaks for itself, and that Bayer does not presently dispute venue.

21. Paragraph 21 of the SAC recites legal conclusions to which no response is required. To the extent that a response is deemed necessary, Bayer denies the allegations contained in Paragraph 21 of the SAC.

22. Paragraph 22 of the SAC recites legal conclusions to which no response is required. To the extent that a response is deemed necessary, Bayer states that the statute referred to in Paragraph 22 of the SAC speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 22 of the SAC.

23. Bayer admits that the Relator purports to bring this action for violation of the FCA, but Bayer denies that the Relator is entitled to maintain this action as alleged or to any relief under the FCA. Bayer lacks knowledge or information sufficient to form a belief as to the truth or falsity of allegations contained in the first sentence of Paragraph 23 of the SAC, and therefore denies the same. Bayer otherwise denies the allegations contained in Paragraph 23 of the SAC.

24. Bayer admits that the Relator worked at Bayer from 1998 through 2004. Bayer otherwise denies the allegations in Paragraph 24 of the SAC.

25. Bayer denies the allegations contained in Paragraph 25 of the SAC.

26. Bayer admits that prior to 2003, Bayer Pharmaceuticals Corporation was located in West Haven, Connecticut, and that it was a subsidiary of Bayer Corporation, which was headquartered in Pittsburgh, Pennsylvania. Bayer otherwise denies the allegations contained in Paragraph 26 of the SAC.

27. Bayer admits that Bayer Corporation was a subsidiary of Bayer AG. Bayer otherwise denies the allegations contained in Paragraph 27 of the SAC.

28. Bayer admits the allegations contained in the first and second sentences of Paragraph 28 of the SAC. Bayer lacks sufficient information or knowledge to form belief as to Relator's meaning of "principal purchasers" and denies the remaining allegations contained in Paragraph 28 of the SAC.

29. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no answer to Paragraph 29 is required. To the extent that a response is deemed necessary, Bayer admits that Paragraph 29 purports to describe the Social Security Act. Bayer states that Relator's characterization is not complete or accurate. Bayer further states that the statute speaks for itself.

30. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no answer to Paragraph 30 is required. To the extent that a response is deemed necessary, Bayer admits that Paragraph 30 purports to describe the Medicaid program. Bayer states that Relator's characterization of the Medicaid program is not complete or accurate.

31. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 31 is required. To the extent that a response is deemed necessary, Bayer admits that Paragraph 31 purports to describe the Federal Employees Health Benefits Plan ("FEHBP"), but states that the Realtor's characterization of FEHBP is not complete or accurate.

32. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 32 is required. To the extent that a response is deemed necessary, Bayer admits that Paragraph 32 purports to describe the TRICARE Program, but states that the Relator's characterization of TRICARE is not complete or accurate. Bayer further states that it lacks the information or knowledge to form an opinion as to the truth or falsity of the allegation contained in the third sentence of Paragraph 32 of the SAC and therefore denies the same.

33. Bayer lacks sufficient information or knowledge to form a belief as to Relator's meaning of "primary objective" and therefore denies the allegations contained in Paragraph 33 of the SAC.

34. Bayer admits that Paragraph 34 of the SAC purports to further describe the TRICARE Program, but lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained within Paragraph 34 and therefore denies the same.

35. Bayer admits that Paragraph 35 of the SAC purports to describe methods for obtaining prescriptions through the TRICARE Program, but states that it lacks sufficient information or knowledge to form a belief as to Relator's meaning of "major methods" and therefore denies the allegations contained in Paragraph 35 of the SAC.

36. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 36 of the SAC, and therefore denies the same.

37. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 37 of the SAC, and therefore denies the same.

38. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 38 of the SAC, and therefore denies the same.

39. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 39 of the SAC, and therefore denies the same.

40. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 40 of the SAC, and therefore denies the same.

41. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 41 of the SAC, and therefore denies the same.

42. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 42 is required. To the extent that a response is deemed necessary, Bayer admits that Paragraph 42 purports to describe the Anti-Kickback Statute, but states that the Relator's characterization of the Anti-Kickback Statute is neither complete nor accurate, and states that the statute speaks for itself.

43. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 43 is required. To the extent that a response is deemed necessary, Bayer admits that Paragraph 43 purports to describe the Anti-Kickback Statute, but states that the Relator's characterization of the Anti-Kickback Statute is neither complete nor accurate, and states that the statute speaks for itself.

44. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 44 is required. To the extent that a response is deemed necessary, Bayer admits that Paragraph 44 purports to describe the Anti-Kickback Statute, but states that the Relator's characterization of the Anti-Kickback Statute is neither complete nor accurate, and states that the statute speaks for itself.

45. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 45 is required. To the extent that a response is deemed necessary, Bayer admits that Paragraph 45 purports to describe the Anti-Kickback Statute, but states that the Relator's characterization of the Anti-Kickback Statute is neither complete nor accurate, and states that the statute speaks for itself.

46. Bayer admits that Paragraph 46 of the SAC purports to describe the FCA, but states that the Relator's characterization of the FCA is neither complete nor accurate, and further states that the statute speaks for itself.

47. Bayer admits that Paragraph 47 of the SAC purports to describe the FCA, but states that the Relator's characterization of the FCA is neither complete nor accurate, and further states that the statute speaks for itself.

48. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 48 is required. To the extent that a response is deemed required, Bayer admits that Paragraph 48 of the SAC purports to describe the FCA, but states that the Relator's characterization of the FCA is neither complete nor accurate, and further states that the statute speaks for itself.

49. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 49 is required. To the extent that a response is deemed required, Bayer admits that Paragraph 49 of the SAC purports to describe state statutes that are analogs of the FCA, but states that the Relator's characterization of the statutes are neither accurate nor complete, and therefore denies the same. Bayer further states that the statutes speak for themselves.

50. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 50 is required. To the extent that a response is deemed required, Bayer admits that Paragraph 50 of the SAC purports to describe federal regulations regarding misbranding, but that the Relator's description of the regulations is neither complete nor accurate, and therefore denies the same. Bayer further states that the regulations speak for themselves.

51. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 51 is required. To the extent that a response is deemed required, Bayer admits that Paragraph 51 of the SAC purports to describe federal regulations regarding labeling, and further states that the regulations speak for themselves, and no response is required.

52. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 52 is required. To the extent a response is deemed required, Bayer admits that Paragraph 52 of the SAC purports to describe federal statutes regarding misbranding, but states that Relator's description of the statutes are neither complete nor accurate, and therefore denies the same. Bayer further states that the statutes speaks for themselves.

53. Bayer admits that Baycol was a statin approved to treat high cholesterol. Bayer admits that Baycol was the sixth statin to enter the market and competed for market share with other statins such as Lipitor.

54. Bayer denies the allegations contained in Paragraph 54 of the SAC.

55. Bayer admits that the product Baycol was introduced in 1998, and that dosage levels of 0.2 – 0.8 mg. were approved by the FDA. Bayer lacks the information or knowledge to form a belief to the allegations contained in the second sentence of Paragraph 55, and therefore denies the same. Bayer further states that it lacks sufficient information or knowledge as to Relator's meaning of "substantial percentages" in the third sentence of Paragraph 55, and therefore denies the same.

56. Bayer admits that it implemented pull-through campaigns at the DoD's request. Bayer lacks sufficient information or knowledge as to Plaintiff's meaning of "significant costs," in the second sentence of Paragraph 56, and therefore denies the same. Bayer otherwise lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 56 of the SAC, and therefore denies the same. To the extent that Paragraph 56 quotes, excerpts, or summarizes a document, Bayer further states that the document speaks for itself.

57. Bayer lacks sufficient information or knowledge as to Plaintiff's meaning of "extremely important," and therefore denies the same. Bayer otherwise admits Paragraph 57 of the SAC.

58. Bayer states that it incorporated the DoD's selection of Baycol for the DoD statin contract into its marketing of Baycol. Bayer further admits that, as required by federal laws regarding government contracting, it priced Baycol competitively when bidding for the DoD statin contract. Bayer otherwise denies the allegations contained in Paragraph 58 of the SAC.

59. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 59 of the SAC, and therefore denies the same.

60. Bayer admits that the Department of Defense ("DoD") issued a solicitation order seeking proposals from manufactures to supply HMG-CoA Reductase Inhibitors (statins) to the Department of Defense. Bayer further states that the solicitation order speaks for itself, and no further response is required.

61. Bayer states that to the extent that Paragraph 61 quotes, excerpts, or summarizes the DoD's solicitation order, that document speaks for itself and no response is required. To the extent that a response is deemed required, Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 61 of the SAC, and therefore denies the same.

62. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 62 of the SAC, and therefore denies the same.

63. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 63 of the SAC, and therefore denies the same.

64. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 64 of the SAC, and therefore denies the same.

65. Bayer lacks sufficient information or knowledge as to Relator's meaning of "extremely lucrative" in Paragraph 65, and therefore denies the same. Bayer further states that it lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 65 of the SAC, and therefore denies the same.

66. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 66 of the SAC, and therefore denies the same.

67. Bayer admits that the DoD awarded the statin contract to Bayer on August 20, 1999. Bayer further states that the document awarding the DoD statin contract to Bayer speaks for itself, and no response is required.

68. Bayer admits that the DoD awarded the contract for the supply of cerivastatin to Bayer on September 1999, and that the DoD listed Baycol on its Basic Core Formulary (“BCF”). Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in the second sentence of Paragraph 68 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 68 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

69. Bayer lacks sufficient information or knowledge as to Relator’s meaning of “workhorse” in Paragraph 69, and therefore denies the same. Bayer further states that it lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 69 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 69 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

70. Bayer admits Paragraph 70 of the SAC. Bayer further states that the contract speaks for itself.

71. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 71 of the SAC, and therefore denies the same.

72. Bayer admits Paragraph 72 of the SAC. Bayer further states that the contract speaks for itself.

73. Bayer admits that the contract contemplated the use of 38,350,000 Baycol tablets per year and that the total contract award with the inclusion of the two extension periods was \$35,665,500. Bayer further states that the contract speaks for itself.

74. Bayer admits Paragraph 74 of the SAC. Bayer further states that the contract speaks for itself.

75. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 75 of the SAC, and therefore denies the same.

76. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 76 of the SAC, and therefore denies the same. Bayer further states that the contract speaks for itself.

77. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 77 of the SAC, and therefore denies the same.

78. Bayer admits the allegations contained in Paragraph 78 of the SAC. Bayer further states that the contract speaks for itself.

79. Bayer admits that LCDR Mark A. Richerson, MSC, USN, Maj. Don DeGroff, MS, USA, and Col. Dan. Remund, MS, USA were among its DoD points of contact for performance of the DoD Baycol Contract.

80. Bayer admits that the DoD decided to exercise its option under the Baycol Contract and extended the performance period through February 19, 2002. Bayer admits that the DoD estimated the value of the contract modification at \$11,888,500. Bayer further states that the contract speaks for itself.

81. Bayer denies the allegations contained in Paragraph 81 of the SAC.

82. Bayer denies that it omitted relevant clinical information in presentations given to the DoD, and denies the allegations contained in Paragraph 82 of the SAC. Bayer admits that the omission of relevant clinical information regarding Baycol to the DoD could have affected the DoD's ability to assess whether to award or extend the Baycol contract.

83. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 83 of the SAC, and therefore denies the same.

84. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 84 of the SAC, and therefore denies the same.

85. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 85 of the SAC, and therefore denies the same. Bayer further states that the contract speaks for itself.

86. Bayer admits that the DoD was aware of Bayer's ongoing clinical trials regarding 0.8mg Baycol tablets, and that the DoD proposed prescribing Baycol at a dosage rate of two 0.4mg tablets per dose. Bayer denies the allegations contained in the fourth sentence of Paragraph 86 of the SAC. Bayer otherwise lacks sufficient information or

knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 86 of the SAC, and therefore denies the same.

87. Bayer denies the allegations contained in Paragraph 87 of the SAC. Bayer further states that to the extent that Paragraph 87 quotes, excerpts, or summarizes a document, the document speaks for itself and no response is required.

88. Bayer admits that the DoD expressed interest in an 0.8 mg dose of Baycol, and that the DoD and Bayer engaged in extensive discussions regarding Baycol's safety. Bayer otherwise lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 88 of the SAC, and therefore denies the same.

89. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 89 of the SAC, and therefore denies the same.

90. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 90 of the SAC, and therefore denies the same.

91. Bayer lacks sufficient information or knowledge as to Relator's "information or belief," and therefore denies the same. Bayer further states that it lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 91 of the SAC, and therefore denies the same.

92. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 92 of the SAC, and

therefore denies the same. Bayer further states that to the extent that Paragraph 92 quotes, excerpts, or summarizes a document, that document speaks for itself.

93. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 93 of the SAC, and therefore denies the same.

94. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 94 of the SAC, and therefore denies the same. Bayer denies the allegations contained in the second sentence of Paragraph 94 of the SAC. Bayer further states that to the extent that Paragraph 94 quotes, excerpts, or summarizes a document, that document speaks for itself.

95. Bayer admits that the DAPA was terminated but lacks sufficient information or knowledge to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 95 of the SAC and otherwise denies the same.

96. Bayer admits that it entered a Blanket Purchase Agreement with the DoD on February 14, 2001 for the supply of 0.8 mg Baycol tablets, and that unit price per tablet was \$0.50. Bayer further states that the Blank Purchase Agreement speaks for itself, and no further response is required.

97. Bayer admits that it entered a Blanket Purchase Agreement for 0.8mg Baycol tablets on February 14, 2001. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of other the allegations contained in Paragraph 97 of the SAC, and therefore denies the same. Bayer further states that the Blanket Purchase Agreement speaks for itself.

98. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 98 of the SAC, and therefore denies the same. Bayer further states that the Blanket Purchase Agreement speaks for itself.

99. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 99 of the SAC, and therefore denies the same.

100. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in the first sentence of Paragraph 100 of the SAC, and therefore denies the same. Bayer denies the allegations contained in the second sentence of Paragraph 100 of the SAC. Bayer further states that to the extent that Paragraph 100 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

101. Bayer admits Paragraph 101. Bayer further states that to the extent that Paragraph 101 of the SAC quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

102. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 102 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 102 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

103. Bayer admits that it engaged in an ongoing conversation with the DoD regarding the safety of Baycol throughout the duration of the DoD contract. Bayer

otherwise lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 103 of the SAC, and therefore denies the same. Bayer further states that it lacks sufficient information or knowledge as to Plaintiff's meaning of "key," in Paragraph 103 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 103 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

104. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 104 of the SAC, and therefore denies the same.

105. Bayer admits that it responded to the DoD's inquiries regarding Baycol's safety. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in the second sentence of Paragraph 105 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 105 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

106. Bayer admits that there was a course of ongoing correspondence between Bayer and the DoD throughout the fall of November 1999 regarding the safety of Baycol, and that DoD requested detailed analysis regarding potential side effects of Baycol. Bayer further states that to the extent that Paragraph 106 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

107. Bayer states that as of November 1999, it did not possess evidence suggesting that Baycol caused rhabdomyolysis at a rate greater than other statins on the market, and

otherwise admits the first sentence of Paragraph 107. Bayer further states that as of November 1999, medical professionals were aware of an association between the use of statins and incidence of rhabdomyolysis. Bayer otherwise denies the allegations contained in Paragraph 107 of the SAC. Bayer further states that to the extent that Paragraph 107 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

108. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in in Paragraph 108 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 108 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

109. Bayer admits that it participated in a conference call regarding Baycol with numerous DoD representatives Baycol on November 24, 1999. Bayer lacks sufficient information or knowledge as to form a belief as to the truth or falsity of the other allegations contained in Paragraph 109 of the SAC, including as to Plaintiff's meaning of "Leading Investigator/Thought Leader," and therefore denies the same. Bayer further states that to the extent that Paragraph 109 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

110. Bayer admits that it sent DoD a letter on December 3, 1999 regarding prescribing practices for Baycol, and that the December 3, 1999 letter reminded the DoD that it had decided to enter a contract for the provision of Baycol because of the product's "proven efficacy and tolerability." Bayer further states that to the extent that Paragraph

110 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

111. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in the first and second sentences of Paragraph 111 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 111 quotes, excerpts, or summarizes a document, that document speaks for itself, and no further response is required. Bayer denies the allegations contained in the third sentence contained in Paragraph 111 of the SAC.

112. Bayer denies the allegations contained in Paragraph 112 of the SAC. Bayer further states that to the extent that Paragraph 112 quotes, excerpts, or summarizes a document, that document speaks for itself, and no further response is required.

113. Bayer admits that it sent a “Dear Doctor” regarding Baycol on December 15, 1999. Bayer otherwise denies the allegations contained in Paragraph 113 of the SAC. Bayer further states that to the extent that Paragraph 113 quotes, excerpts, or summarizes a document, that document speaks for itself, and no further response is required.

114. Bayer denies the allegations contained in Paragraph 114 of the SAC.

115. Bayer denies the allegations contained in Paragraph 115 of the SAC.

116. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 116, and therefore denies the same. Bayer further states that to the extent that Paragraph 116 quotes, excerpts, or summarizes a document, that document speaks for itself, and no further response is required.

117. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 117 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 117 quotes, excerpts, or summarizes a document, that document speaks for itself, and no further response is required.

118. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 118 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 118 quotes, excerpts, or summarizes a document, that document speaks for itself, and no further response is required.

119. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 119 of the SAC, and therefore denies the same.

120. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 120 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 120 quotes, excerpts, or summarizes a document, that document speaks for itself, and no further response is required.

121. Bayer denies the allegations contained in Paragraph 121 of the SAC.

122. Bayer denies the allegations contained in Paragraph 122 of the SAC. Bayer further states that to the extent that Paragraph 122 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

123. Bayer admits that it has stated that the warnings for Baycol were adequate to describe potential side effects. Bayer denies the other allegations contained in Paragraph 123 of the SAC.

124. Bayer denies the allegations contained in Paragraph 124 of the SAC.

125. Bayer denies the allegations contained in Paragraph 125 of the SAC.

126. Bayer denies the allegations contained in Paragraph 126 of the SAC.

127. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 127 of the SAC, and therefore denies the same.

128. Bayer admits that Pacificare conducted a study regarding Baycol's safety as compared to other statins on the market, and that Bayer utilized the results of the Pacificare study in promoting Baycol. Bayer otherwise denies the allegations contained in Paragraph 128 of the SAC.

129. Bayer denies the allegations contained in Paragraph 129 of the SAC.

130. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 130 of the SAC, and therefore denies the same.

131. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 131 of the SAC, and therefore denies the same.

132. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 132 of the SAC, and therefore denies the same.

133. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 133 of the SAC, and therefore denies the same.

134. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 134 of the SAC, and therefore denies the same.

135. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 135 of the SAC, and therefore denies the same.

136. Bayer denies the allegations contained in Paragraph 136 of the SAC.

137. Bayer denies the allegations contained in Paragraph 137 of the SAC.

138. Bayer denies the allegations contained in Paragraph 138 of the SAC.

139. Bayer denies the allegations contained in Paragraph 139 of the SAC.

140. Bayer admits that the statins on the market at and around the time of the Baycol launch, including Baycol, were considered safe and effective products that had received FDA approval. Bayer otherwise states that it lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 140 of the SAC, and therefore denies the same. Bayer further states that it lacks sufficient

information regarding Plaintiff's reference to "relatively safe," and therefore denies the same.

141. Bayer denies the allegations contained in Paragraph 141 of the SAC.

142. Bayer denies the allegations contained in Paragraph 142 of the SAC. Bayer further states that to the extent that Paragraph 142 quotes, excerpts, or summarizes a document, that document speaks for itself, and no further response is required.

143. Bayer denies the allegations contained in Paragraph 143 of the SAC.

144. Bayer denies the allegations contained in Paragraph 144 of the SAC.

145. Bayer denies the allegations contained in Paragraph 145 of the SAC. Bayer further states that to the extent that Paragraph 145 quotes, excerpts, or summarizes a document, that document speaks for itself, and no further response is required.

146. Bayer denies the allegations contained in Paragraph 146 of the SAC.

147. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity as to documents that Plaintiff "believed to be misleading," and therefore denies the same. Bayer denies the allegations contained in the second sentence of Paragraph 147 of the SAC.

148. Bayer denies the allegations contained in Paragraph 148 of the SAC.

149. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in the first sentence of Paragraph 149 of the SAC, and therefore denies the same. Bayer further states that it lacks sufficient information or knowledge as to Plaintiff's meaning of "homemade bread," and therefore denies the

same. Bayer denies the allegations contained in the second sentence of Paragraph 149 of the SAC.

150. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in the first sentence of Paragraph 150. Bayer further states that it lacks sufficient information or knowledge as to Plaintiff's meaning of "homemade bread," and therefore denies the same. To the extent that Paragraph 150 quotes, excerpts, or summarizes a document, that document speaks for itself, and no further response is required. Bayer otherwise denies the allegations contained in Paragraph 150 of the SAC.

151. Bayer denies the allegations contained in Paragraph 151 of the SAC.

152. Bayer denies the allegations contained in Paragraph 152 of the SAC. Bayer further states that to the extent that Paragraph 152 quotes, excerpts, or summarizes a document, that document speaks for itself, and no further response is required.

153. Bayer denies the allegations contained in Paragraph 153 of the SAC.

154. Bayer denies the allegations contained in Paragraph 154 of the SAC.

155. Bayer denies the allegations contained in Paragraph 155 of the SAC.

156. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 156 of the SAC and therefore denies the same. Bayer further states that to the extent that Paragraph 156 quotes, excerpts, or summarizes a document, that document speaks for itself, and no other response is required.

157. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 157 of the SAC, and therefore denies the same.

158. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 158 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 158 quotes, excerpts, or summarizes a document, that document speaks for itself, and no other response is required.

159. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 159 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 159 quotes, excerpts, or summarizes a document, that document speaks for itself, and no other response is required.

160. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 160 of the SAC, and therefore denies the same. Bayer further states that to the extent Paragraph 160 quotes, excerpts, or summarizes a document, that document speaks for itself, and no other response is required.

161. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 161 of the SAC, and therefore denies the same. Bayer further states that to the extent Paragraph 161 quotes, excerpts, or summarizes a document, that document speaks for itself, and no other response is required.

162. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 162 of the SAC, and therefore denies the same. Bayer further states that to the extent Paragraph 162, or the footnote to Paragraph 162, is deemed to quote or excerpt a document, that document speaks for itself, and no other response is required.

163. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 163 of the SAC, and therefore denies the same. Bayer further states that to the extent Paragraph 163, or the footnote to Paragraph 163, is deemed to quote or excerpt a document, that document speaks for itself, and no other response is required.

164. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 164 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 164 quotes, excerpts, or summarizes a document, that document speaks for itself, and no other response is required.

165. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 165 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 165 quotes, excerpts, or summarizes a document, that document speaks for itself, and no other response is required.

166. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 166 of the SAC, and therefore

denies the same. Bayer further states that to the extent that Paragraph 166 quotes, excerpts, or summarizes a document, that document speaks for itself, and no other response is required.

167. Bayer states that the labeling for Baycol prescribed by the FDA included a warning about the combined use of cerivastatin and fibrates. Bayer otherwise lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 167 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 167 quotes, excerpts, or summarizes a document, that document speaks for itself, and no response is required.

168. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 168 of the SAC, and denies the same. Bayer further states that to the extent that Paragraph 168 quotes, excerpts, or summarizes a document, that document speaks for itself, and no response is required.

169. Bayer admits that added a contraindication to the Baycol labeling in December 1999, and that it distributed a letter to healthcare professionals about the Baycol contraindication on December 15, 1999. Bayer otherwise denies the allegations contained in Paragraph 169 of the SAC. Bayer further states that to the extent that Paragraph 169 quotes, excerpts or summarizes a document, that document speaks for itself and no further response is required.

170. Bayer denies the allegations contained in Paragraph 170 of the SAC. Bayer further states that to the extent that Paragraph 170 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

171. Bayer denies the allegations contained in Paragraph 171 of the SAC.

172. Bayer denies the allegations contained in Paragraph 172 of the SAC. Bayer further states that to the extent that Paragraph 172 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

173. Bayer denies the allegations contained in Paragraph 173 of the SAC.

174. Bayer denies the allegations contained in Paragraph 174 of the SAC. Bayer further states that to the extent that Paragraph 174 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

175. Bayer lacks sufficient information or knowledge at this time to form a belief as to the truth or falsity of the allegations contained in Paragraph 175 of the SAC, and therefore denies the same.

176. Bayer denies the allegations contained in Paragraph 176 of the SAC. Bayer further states that to the extent that Paragraph 176 quotes, excerpts, or summarizes a document, that document speaks for itself, and no response is required.

177. Bayer denies the allegations contained in Paragraph 177 of the SAC.

178. Bayer denies the allegations contained in Paragraph 178 of the SAC. Bayer further states that to the extent that Paragraph 178, or the footnote in Paragraph 178, quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

179. Bayer lacks sufficient information or knowledge to form an opinion as to the truth or falsity of the allegations contained in Paragraph 179 of the SAC, and therefore denies the same.

180. Bayer denies the allegations contained in Paragraph 180 of the SAC.

181. Bayer denies the allegations contained in Paragraph 181 of the SAC. Bayer further states that to the extent that Paragraph 181 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

182. Bayer denies the allegations contained in Paragraph 182 of the SAC. Bayer further states that to the extent that Paragraph 182, or the footnote contained in Paragraph 182, quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

183. Bayer admits that the recommended starting dose for Baycol was 0.4 mg. Bayer otherwise denies the allegations contained in Paragraph 183 of the SAC. Bayer further states that to the extent that Paragraph 183 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

184. The first sentence of Paragraph 184 contains legal conclusions, to which no response is required. To the extent that a response is deemed required, Bayer states that without citations it cannot form an opinion as to the truth or falsity of the allegations contained in the first sentence of Paragraph 184 and therefore denies the same. Bayer further states that to the extent that Paragraph 184 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required. Bayer otherwise denies the allegations contained in Paragraph 184 of the SAC.

185. Bayer denies the allegations contained in Paragraph 185 of the SAC.

186. Bayer denies the allegations contained in Paragraph 186 of the SAC.

187. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 187 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 187 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

188. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 188 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 188 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

189. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 189 of the SAC, and therefore denies the same.

190. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 190 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 190 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

191. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 191 of the SAC, and therefore denies the same.

192. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 192 of the SAC, and therefore denies the same.

193. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 193 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 193 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

194. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 194 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 194 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

195. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 195 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 195 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

196. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 196 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 196 quotes, excerpts,

or summarizes a document, that document speaks for itself and no further response is required.

197. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity as to the Relator's presence at a Bayer global marketing meeting, and therefore denies the same. Bayer denies the other allegations contained in Paragraph 197 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 197 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

198. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 198 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 198 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

199. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 199 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 199 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

200. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 200 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 200 quotes, excerpts,

or summarizes a document, that document speaks for itself and no further response is required.

201. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 201 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 201 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

202. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 202 of the SAC, and therefore denies the same.

203. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 203 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 203 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

204. Bayer denies the allegations contained in Paragraph 204 of the SAC.

205. Bayer denies the allegations contained in Paragraph 205 of the SAC.

206. Bayer denies the allegations contained in Paragraph 206 of the SAC.

207. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 207 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 207 of the SAC.

208. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 208 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 208 of the SAC.

209. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 209 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 209 of the SAC. Bayer further states that to the extent that Paragraph 209 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

210. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 210 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 210 of the SAC.

211. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 211 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 211 of the SAC. Bayer further states that to the extent that Paragraph 211 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

212. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph

212 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 212 of the SAC. Bayer further states that to the extent that Paragraph 212 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

213. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 213 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 213 of the SAC. Bayer further states that to the extent that Paragraph 213 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

214. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 214 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 214 of the SAC. Bayer further states that to the extent that Paragraph 214, or Exhibit A as referenced in Paragraph 214, quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

215. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 215 is required. To the extent that a response is deemed required, Bayer lacks sufficient information to form a belief as to the truth or falsity of the allegations contained in Paragraph 215, and therefore denies the same.

216. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 216 is required. To the extent that a response is deemed required, Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 216, and therefore denies the same.

217. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 217 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 217 of the SAC. Bayer further states that to the extent that Paragraph 217 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

218. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 218 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 218 of the SAC. Bayer further states that to the extent that Paragraph 218 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

219. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 219 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 219 of the SAC. Bayer further states that to the extent

that Paragraph 219 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

220. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 220 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 220 of the SAC.

221. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 221 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 221 of the SAC.

222. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 222 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 222 of the SAC.

223. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 223 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 223 of the SAC. Bayer further states that to the extent that Paragraph 223 quotes, excerpts, or summarizes a document, that document speaks for itself and no further response is required.

224. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph

224 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 224 of the SAC.

225. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 225 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 225 of the SAC. Bayer further states that to the extent that Paragraph 225 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

226. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 226 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 226 of the SAC. Bayer further states that to the extent that Paragraph 226 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

227. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 227 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 227 of the SAC. Bayer further states that to the extent that Paragraph 227 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

228. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph

228 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 228 of the SAC. Bayer further states that to the extent that Paragraph 228 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

229. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 229 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 229 of the SAC.

230. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 230 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 230 of the SAC. Bayer further states that to the extent that Paragraph 230 quotes, summarizes, or excerpts a document, that document speaks for itself and no response is required.

231. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 231 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 231 of the SAC. Bayer further states that to the extent that Paragraph 231 quotes, summarizes, or excerpts a document, that document speaks for itself and no response is required.

232. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph

232 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 232 of the SAC.

233. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 233 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 233 of the SAC. Bayer further states that to the extent that Paragraph 233 quotes, summarizes, or excerpts a document, that document speaks for itself and no response is required.

234. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 234 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 234 of the SAC.

235. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 235 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 235 of the SAC. Bayer further states that to the extent that Paragraph 235 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

236. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 236 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 236 of the SAC. Bayer further states that to the extent

that Paragraph 236 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

237. Bayer denies the allegations contained in Paragraph 237 of the SAC.

238. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 238 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 238 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

239. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 239 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 239 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

240. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 240 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 240 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

241. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 241 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 241 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

242. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 242 of the SAC, and therefore

denies the same. Bayer further states that to the extent that Paragraph 242 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

243. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 243 of the SAC, and therefore denies the same.

244. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 189 of the SAC, and therefore denies the same.

245. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 189 of the SAC, and therefore denies the same.

246. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 246 of the SAC, and therefore denies the same.

247. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 247 of the SAC, and therefore denies the same.

248. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 248 of the SAC, and therefore denies the same.

249. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph

249 is required. To the extent that a response is deemed required, Bayer states that Paragraph 249 contains a legal conclusion to which no response is required.

250. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 250 is required. To the extent that a response is deemed required, Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 250 of the SAC, and therefore denies the same.

251. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 251 is required. To the extent that a response is deemed required, Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 251 of the SAC, and therefore denies the same.

252. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 249 is required. To the extent that a response is deemed required, Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 252 of the SAC, and therefore denies the same.

253. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 253 of the SAC, and therefore denies the same.

254. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph

254 is required. To the extent that a response is deemed required, Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 254 of the SAC, and therefore denies the same.

255. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 255 is required. To the extent that a response is deemed required, Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 255 of the SAC, and therefore denies the same.

256. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 256 is required. To the extent that a response is deemed required, Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 256 of the SAC, and therefore denies the same.

257. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 257 of the SAC, and therefore denies the same.

258. Bayer lacks sufficient information or knowledge to form a belief as to Plaintiff's meaning of "significant proportion" in the first sentence of Paragraph 258, and therefore denies the same. Bayer further states that at this time it lacks sufficient information to form a belief as to the truth or falsity of the allegations contained in Paragraph 258 of the SAC, and therefore denies the same.

259. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 259 of the SAC, and therefore denies the same. Bayer further states that to the extent that Paragraph 259 quotes, excerpts, or summarizes a document, that document speaks for itself and no response is required.

260. Bayer lacks sufficient information or knowledge to form a belief as to the truth or falsity of the allegations contained in Paragraph 260 of the SAC, and therefore denies the same.

261. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 261 is required. To the extent that a response is deemed required, Bayer admits that it voluntarily withdrew Baycol from the market, and otherwise denies the allegations contained in Paragraph 261 of the SAC.

262. Bayer denies the allegations contained in Paragraph 262 of the SAC.

263. Bayer admits that it voluntarily withdrew Baycol from the market, and admits that it received a communication from the FDA about Baycol in 2001, but otherwise denies the allegations contained in Paragraph 263 of the SAC. To the extent that this Paragraph summarizes the content of a FDA communication, Bayer states that the document speaks for itself, and no response is required.

264. Bayer denies the allegations contained in Paragraph 264 of the SAC.

265. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph

265 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 265 of the SAC.

266. Bayer denies the allegations contained in Paragraph 266 of the SAC.

267. Bayer denies the allegations contained in Paragraph 267 of the SAC.

268. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 268 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 268 of the SAC.

269. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 269 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 269 of the SAC.

270. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 270 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 270 of the SAC.

CLAIMS FOR RELIEF
FIRST CAUSE OF ACTION
False Claims Act: Presentation of False Claims
31 U.S.C. § 3729(a)(1)

271. Bayer incorporates by reference its statements made in the foregoing paragraphs. Bayer further states that it denies the allegations contained in Paragraph 271 of the SAC.

SECOND CAUSE OF ACTION
False Claims Act: Making or Using False
Record or Statement to Cause Claim to Be Paid
31 U.S.C. § 3729(a)(2)

272. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 272 is required. To the extent that a response is deemed required, Bayer incorporates by reference its statements made in the foregoing paragraphs, and further states that it denies the allegations contained in Paragraph 272 of the SAC.

273. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 273 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 273 of the SAC.

274. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 274 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 274 of the SAC.

275. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 275 is required. To the extent that a response is deemed required, Bayer denies the allegations contained in Paragraph 275 of the SAC.

THIRD CAUSE OF ACTION
California False Claims Act
Cal. Govt. Code § 12651(a)

276. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 276 is required. To the extent that a response is deemed required, Bayer admits that Relator purports to state a claim under the California False Claims Act, and that Paragraph 276 of the SAC purports to describe the California False Claims Act. Bayer states that Relator's description of the statute is neither complete nor accurate, and further states that the statute speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 276 of the SAC.

277. Bayer denies the allegations contained in Paragraph 277 of the SAC.

278. Bayer denies the allegations contained in Paragraph 278 of the SAC.

279. Bayer denies the allegations contained in Paragraph 279 of the SAC.

280. Bayer denies the allegations contained in Paragraph 280 of the SAC.

281. Bayer admits that Paragraph 281 purports to describe the penalty provisions of the California False Claim Act, but states that the statute speaks for itself and no response is required. To the extent that a response is deemed necessary, Bayer denies the allegations contained in Paragraph 281 of the SAC.

FOURTH CAUSE OF ACTION
Delaware False Claims and Reporting Act
6 Del C. § 1201(a)

282. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 282 is required. To the extent a response is deemed required, Bayer admits that Relator purports to state a claim under the Delaware False Claims and Reporting Act, and that

Paragraph 282 of the SAC purports to describe the Delaware False Claims and Reporting Act. Bayer states that Relator's description of the statute is neither complete nor accurate, and further states that the statute speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 282 of the SAC.

283. Bayer denies the allegations contained in Paragraph 283 of the SAC.

284. Bayer denies the allegations contained in Paragraph 284 of the SAC.

285. Bayer denies the allegations contained in Paragraph 285 of the SAC.

286. Bayer denies the allegations contained in Paragraph 286 of the SAC.

287. Bayer admits that Paragraph 287 purports to describe the penalty provisions of the Delaware False Claims and Reporting Act, but states that the statute speaks for itself and no response is required. To the extent that a response is deemed necessary, Bayer denies the allegations contained in Paragraph 287 of the SAC.

FIFTH CAUSE OF ACTION
Florida False Claims Act
Fla. Stat. Ann. § 68.082(2)

288. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 288 is required. To the extent that a response is deemed required, Bayer admits that the Relator purports to state a claim under the Florida False Claims Act, and that Paragraph 288 purports to describe the Florida False Claims Act. Bayer states that the Relator's description of the statute is neither complete nor accurate, and further states that the statute speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 288 of the SAC.

289. Bayer denies the allegations contained in Paragraph 289 of the SAC.

290. Bayer denies the allegations contained in Paragraph 290 of the SAC.

291. Bayer denies the allegations contained in Paragraph 291 of the SAC.

292. Bayer denies the allegations contained in Paragraph 292 of the SAC.

293. Bayer admits that Paragraph 293 purports to describe the penalty provisions of the Florida False Claims Act, but states that the statute speaks for itself, and no response is required. To the extent that a response is deemed necessary, Bayer denies the allegations contained in Paragraph 293 of the SAC.

SIXTH CAUSE OF ACTION
Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)

294. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 294 is required. To the extent that a response is deemed required, Bayer admits that the Relator purports to state a claim under the Hawaii False Claims Act, and that Paragraph 294 purports to describe the Hawaii False Claims Act. Bayer states that the Relator's description of the statute is neither complete nor accurate, and further states that the statute speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 294 of the SAC.

295. Bayer denies the allegations contained in Paragraph 295 of the SAC.

296. Bayer denies the allegations contained in Paragraph 296 of the SAC.

297. Bayer denies the allegations contained in Paragraph 297 of the SAC.

298. Bayer admits that Paragraph 298 purports to describe the penalty provisions of the Hawaii False Claims Act, but states that the statute speaks for itself, and no response is required. To the extent a response is deemed necessary, Bayer denies the allegations contained in Paragraph 298 of the SAC.

SEVENTH CAUSE OF ACTION
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. § 175/3(a)

299. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 299 is required. To the extent that a response is deemed required, Bayer admits that the Relator purports to state a claim under the Illinois Whistleblower Reward and Protection Act, and that Paragraph 299 purports to describe the same. Bayer states that the Relator's description of the statute is neither complete nor accurate, and further states that the statute speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 299 of the SAC.

300. Bayer denies the allegations contained in Paragraph 300 of the SAC.

301. Bayer denies the allegations contained in Paragraph 301 of the SAC.

302. Bayer denies the allegations contained in Paragraph 302 of the SAC.

303. Bayer denies the allegations contained in Paragraph 303 of the SAC.

304. Bayer admits that Paragraph 304 purports to describe the penalty provisions of the Illinois Whistleblower Reward and Protection Act, but states that the statute speaks for itself, and no response is required. To the extent a response is deemed necessary, Bayer denies the allegations contained in Paragraph 304 of the SAC.

EIGHTH CAUSE OF ACTION
Louisiana False Claims Act / Medical Assistance Programs Integrity Law
46 La. Rev. Stat. c.3 § 438

305. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 305 is required. To the extent that a response is deemed required, Bayer admits that the Relator purports to state a claim under the Louisiana False Claims Act and Medical Assistance Programs Integrity Law, and that Paragraph 288 purports to describe the same. Bayer states that the Relator's description of the statute is neither complete nor accurate, and further states that the statute speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 305 of the SAC.

306. Bayer denies the allegations contained in Paragraph 306 of the SAC.

307. Bayer denies the allegations contained in Paragraph 307 of the SAC.

308. Bayer denies the allegations contained in Paragraph 308 of the SAC.

309. Bayer admits that Paragraph 309 purports to describe the penalty provisions of the Louisiana False Claims Act and Medical Programs Integrity Law, but states that the statute speaks for itself, and no response is required. To the extent a response is deemed necessary, Bayer denies the allegations contained in Paragraph 309 of the SAC.

NINTH CAUSE OF ACTION
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 § 5B

310. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 310 is required. To the extent that a response is deemed required, Bayer admits that the

Relator purports to state a claim under the Massachusetts False Claims Law, and that Paragraph 288 purports to describe the Massachusetts False Claims Law. Bayer states that the Relator's description of the statute is neither complete nor accurate, and further states that the statute speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 310 of the SAC.

311. Bayer denies the allegations contained in Paragraph 311 of the SAC.

312. Bayer denies the allegations contained in Paragraph 312 of the SAC.

313. Bayer denies the allegations contained in Paragraph 313 of the SAC.

314. Bayer denies the allegations contained in Paragraph 314 of the SAC.

315. Bayer admits that Paragraph 315 purports to describe the penalty provisions of the Massachusetts False Claims Law, but states that the statute speaks for itself, and no response is required. To the extent a response is deemed necessary, Bayer denies the allegations contained in Paragraph 315 of the SAC.

TENTH CAUSE OF ACTION
Nevada False Claims Act
Nev. Rev. Stat. Ann. § 357.040(1)

316. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 316 is required. To the extent that a response is deemed required, Bayer admits that the Relator purports to state a claim under the Nevada False Claims Act, and that Paragraph 316 purports to describe the Nevada False Claims Act. Bayer states that the Relator's description of the statute is neither complete nor accurate, and further states that the statute

speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 316 of the SAC.

317. Bayer denies the allegations contained in Paragraph 317 of the SAC.

318. Bayer denies the allegations contained in Paragraph 318 of the SAC.

319. Bayer denies the allegations contained in Paragraph 319 of the SAC.

320. Bayer denies the allegations contained in Paragraph 320 of the SAC.

321. Bayer admits that Paragraph 321 purports to describe the penalty provisions of the Nevada False Claims Act, but states that the statute speaks for itself, and no response is required. To the extent a response is deemed necessary, Bayer denies the allegations contained in Paragraph 321 of the SAC.

**ELEVENTH CAUSE OF ACTION
Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)**

322. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 322 is required. To the extent that a response is deemed required, Bayer admits that the Relator purports to state a claim under the Tennessee Medicaid False Claims Act, and that Paragraph 322 purports to describe the Tennessee Medicaid False Claims Act. Bayer states that the Relator's description of the statute is neither complete nor accurate, and further states that the statute speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 322 of the SAC.

323. Bayer denies the allegations contained in Paragraph 323 of the SAC.

324. Bayer denies the allegations contained in Paragraph 324 of the SAC.

325. Bayer denies the allegations contained in Paragraph 325 of the SAC.

326. Bayer denies the allegations contained in Paragraph 326 of the SAC.

327. Bayer admits that Paragraph 327 purports to describe the penalty provisions of the Tennessee Medicate False Claims Act, but states that the statute speaks for itself, and no response is required. To the extent a response is deemed necessary, Bayer denies the allegations contained in Paragraph 327 of the SAC.

TWELFTH CAUSE OF ACTION
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.002

328. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 328 is required. To the extent that a response is deemed required, Bayer admits that the Relator purports to state a claim under the Texas Medicaid Fraud Prevention Law, and that Paragraph 328 purports to describe the Texas Medicaid Fraud Prevention Law. Bayer states that the Relator's description of the statute is neither complete nor accurate, and further states that the statute speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 328 of the SAC.

329. Bayer denies the allegations contained in Paragraph 329 of the SAC.

330. Bayer denies the allegations contained in Paragraph 330 of the SAC.

331. Bayer denies the allegations contained in Paragraph 331 of the SAC.

332. Bayer denies the allegations contained in Paragraph 332 of the SAC.

333. Bayer admits that Paragraph 333 purports to describe the penalty provisions of the Texas Medicaid Fraud Prevention Law, but states that the statute speaks for itself,

and no response is required. To the extent a response is deemed necessary, Bayer denies the allegations contained in Paragraph 333 of the SAC.

THIRTEENTH CAUSE OF ACTION
District of Columbia False Claims Act
D.C. Code Ann. § 2-308.03 *et seq.* (formerly § 1-1188.14, *et seq.*)

334. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph 334 is required. To the extent that a response is deemed required, Bayer admits that the Relator purports to state a claim under the D.C. False Claims Act, and that Paragraph 334 purports to describe the D.C. False Claims Act. Bayer states that the Relator's description of the statute is neither complete nor accurate, and further states that the statute speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 334 of the SAC.

335. Bayer denies the allegations contained in Paragraph 335 of the SAC.

336. Bayer denies the allegations contained in Paragraph 336 of the SAC.

337. Bayer denies the allegations contained in Paragraph 337 of the SAC.

338. Bayer admits that Paragraph 338 purports to describe the penalty provisions of the D.C. False Claims Act, but states that the statute speaks for itself, and no response is required. To the extent a response is deemed necessary, Bayer denies the allegations contained in Paragraph 338 of the SAC.

FOURTEENTH CAUSE OF ACTION
New York False Claims Act
N.Y. Finance Law § 187, *et seq.*

339. Bayer states that Relator's claims (Counts 2 – 14) concerning misbranding and kickbacks have been dismissed with prejudice, and therefore no response to Paragraph

339 is required. To the extent that a response is deemed required, Bayer admits that the Relator purports to state a claim under the New York False Claims Act, and that Paragraph 339 purports to describe the New York False Claims Act. Bayer states that the Relator's description of the statute is neither complete nor accurate, and further states that the statute speaks for itself. Bayer otherwise denies the allegations contained in Paragraph 339 of the SAC.

340. Bayer denies the allegations contained in Paragraph 340 of the SAC.

341. Bayer denies the allegations contained in Paragraph 341 of the SAC.

342. Bayer denies the allegations contained in Paragraph 342 of the SAC.

343. Bayer denies the allegations contained in Paragraph 343 of the SAC.

344. Bayer admits that Paragraph 344 purports to describe the penalty provisions of the New York False Claims Act, but states that the statute speaks for itself, and no response is required. To the extent a response is deemed necessary, Bayer denies the allegations contained in Paragraph 344 of the SAC.

GENERAL DENIAL AND RESPONSE TO RELATOR'S PRAYER FOR RELIEF

345. Except as specifically admitted herein, Bayer denies each and every allegation of the SAC. To the extent any headings or footnotes in the SAC are considered separate allegations, Bayer denies them. Bayer further denies that Relator is entitled to a judgment or any relief whatsoever, whether requested in the prayer for relief and in the paragraphs following Paragraph 344 of the SAC, or otherwise. Relator's prayer for relief should be denied in its entirety and Relator should take nothing from Bayer. Bayer asks that judgement be entered for Bayer and that Bayer be awarded its attorneys' fees in

defending against the SAC, together with costs and other such relief as the Court deems appropriate.

DEFENSES

Bayer hereby states the following defenses and affirmative defenses, without assuming the burden of proof regarding any, and reserves the right to assert additional defenses when they become appropriate.

First Defense

Each and every count of the SAC fails to state a claim and is barred, in whole and/or in part, including because Bayer's alleged conduct did not involve any "false or fraudulent" claim, was not material, was not the cause (proximate and/or competent cause) of an alleged harm, and/or did not cause damages.

Second Defense

The Court lacks subject matter jurisdiction, including to the extent Bayer's allegations and claims are based, in whole or in part, on publicly-disclosed information of which Relator is not an original source, or concern matters not voluntarily disclosed by Relator to the applicable government authority prior to the filing of the action.

Third Defense

Relator's claims are barred, in whole and/or in part, by the applicable statutes of limitations, borrowing statutes, and/or statutes of repose.

Fourth Defense

Relator's claims are barred, in whole and/or in part, because the alleged injuries and damages, if any, resulted from an intervening or superseding cause and/or causes, including, but not limited to, the actions of learned intermediaries such as physicians.

Fifth Defense

Relator's claims are barred, in whole and/or in part, because acts or omissions of alleged wrongdoing or violations of law were committed by individuals acting *ultra vires*, outside the scope of their employment or authority, and/or in a manner inconsistent with Bayer policy.

Sixth Defense

Relator's claims are barred, in whole and/or in part, because the acts or omissions of other persons or entities, whether or not named or unnamed in the SAC, over whom Bayer had no supervision or control and for whose actions and omissions Bayer has no legal responsibility, caused and/or contributed to the alleged damages.

Seventh Defense

Relator's claims are barred, in whole and/or in part, because the applicable federal, state, or city government, agency, department, agent, employee, or official expressly or implicitly approved, ratified, or otherwise consent to, or acted with knowledge of, the conduct, transactions, and/or occurrences that are the subject of the SAC.

Eighth Defense

Relator's claims are barred, in whole and/or in part, because any actions taken by Bayer with respect to the subject matters alleged by Relator were objectively reasonable,

taken in good faith, in accordance and consistent with medical ethical obligations, and/or constituted lawful, proper, justified, and/or privileged conduct.

Ninth Defense

Relator's claims are barred, in whole and/or in part, insofar as such claims are based on, or would punish or deter, alleged conduct that is protected under the First Amendment to the United States constitution and/or by applicable state statutory and constitutional provisions protective speech.

Tenth Defense

Relator's claims and/or the imposition of penalties are barred, in whole and/or in part, because the statutes, rules, or regulations upon which Relator's claims are based are unconstitutionally vague and/or overbroad.

Eleventh Defense

Any damages and/or penalties Relator seeks above and beyond actual damages, if any, allegedly sustained are in excess of those permitted by law, and violative of the United States Constitution (including the Due Process and Excessive Fines Clauses) and applicable state constitutions.

Twelfth Defense

The alleged damages are too remote and speculative to form the basis for relief.

Thirteenth Defense

Relator's claims are barred, in whole or in part, by the doctrines of laches, waiver, and/or estoppel.

Fourteenth Defense

Relator's claims are barred by the doctrine of unclean hands.

Fifteenth Defense

Relator's state law claims are barred, in whole and/or in part, because Relator lacks standing under applicable state statutes.

Sixteenth Defense

Relator's state law claims are barred to the extent applicable law requires that such claims be brought in the state in which the challenged conduct allegedly occurred.

Seventeenth Defense

Bayer preserves all defenses relating to personal jurisdiction as to allegations or claims arising from events that occurred outside of Minnesota and/or New Jersey.

* * *

Bayer reserves the right to amend these defenses and to assert additional defenses during the course of this action.

JURY TRIAL DEMAND

Bayer demands a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Bayer, having fully answered the Second Amended Complain, prays that the Court:

1. Enter judgment in favor of Bayer, deny Relator Simpson's requested relief in its entirety, and order that Relator Simpson shall recover nothing;

2. Award Bayer the costs incurred to defend this action, including reasonable attorneys' fees;
3. Award such other relief as this court deems just and proper.

DATED: January 15, 2019

Respectfully submitted,

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